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21 JAN 2008

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Application No. 03 739 861.7 - 1214	Ref. CSM68535	Date 18.01.2008
Applicant Polynovo Biomaterials Pty Limited		

#### Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).



Bourgonje, Andreas  
Primary Examiner  
for the Examining Division

Enclosure(s): 34 pages reasons (Form 2906)

The examination is being carried out on the following application documents:

**Description, Pages**

1-55 as originally filed

**Claims, Numbers**

11-26 as originally filed

1-10, 27, 28 received on 21.11.2006 with letter of 15.11.2006

**Drawings, Figures**

1-18 as originally filed

1 The following documents are referred to in this communication:

- D1: US-A-5 578 662 (BENNETT ET AL) 26 November 1996 (1996-11-26)
- D2: WO 02/36695 A (BASF DRUCKSYSTEME) 10 May 2002 (2002-05-10)
- D3: US-B1-6 376 742 (ZDRAHALA ET AL) 23 April 2002 (2002-04-23)
- D4: ZHANG ET AL: "Synthesis, Biodegradability and Biocompatibility of Lysine Diisocyanate-Glucose Polymers" TISSUE ENGINEERING, vol. 8, no. 5, October 2002 (2002-10), pages 771-785, XP008059981
- D5: EP-A2-0 837 084
- \* D6: GB-A-2 067 580 (NL Industries) 30 July 1981 (1981-07-30)

≡ 05 4,284,506

## 2 Clarity and Support

2.1 Although the amendments of the claims introduced by the applicants letter of 15-11-2006 would appear to be supported by the description and fulfil the requirements of Article 123 (2) EPC they also introduce unclarity because the terms 'biocompatible' and 'injectable' have no well defined meaning and therefore can not clearly define the subject matter for which protection is sought. The terms 'flowable' and 'injectable' would appear to point to a certain viscosity/liquidity of the material in question but no conditions are mentioned (temperature, apparatus to measure) in the claims nor in the description as to how to establish whether a material would fulfil the requirement for 'flowability' or 'injectability'. The same argument is valid for the term 'biocompatible' in amended claim 1 and further claims. These unclear terms can not be used to distinguish the invention from the prior art (Guidelines, Part C, III, 4.2 and 4.6).

2.2 The viscosity in claim 6 is given in cSt which is not a unit recognized in international practice and does not comply with Rule 49 (10) EPC. Values should be given in SI-units (Poise).

2.3 A writing/typing error in claim 10 has to be corrected ('2,6-dihocyanato').

## 3 Novelty

3.1 The Appendices 1 and 2 of your letter of 15-11-2006 depict chemical structures of cured polymers but the claims 1-7 of the present invention only refer to a prepolymer.

3.2 As explained under 2.1 the terms 'flowable' and 'injectable' are not sufficiently clear to establish novelty over the prior art because they have no well recognized meaning. The document D1 therefore is still considered to be novelty destroying towards the subject matter of claims 1,2,4,5,7,11-13,23,24,26 according to the same arguments as brought forward in the communication of 06-07-2006 point 2.2

3.3 Document D2 discloses hyperbranched reaction products of diisocyanates and multifunctional core molecules having hydroxyl groups (examples, D2). The subject matter of claims 1-5 is therefore not novel according to Article 54, EPC.

3.4 Document D3 discloses cartilage or bone repair compositions prepared from prepolymers based on hexanediisocyanate and TMP (example 3, D3), this prepolymer then reacts with soft segment introducing polymers like glycerine started polycaprolactones (column 9, lines 24-39, D3). Inclusion of sodium chloride salts is disclosed (column 9, line 66, D3) leading to compositions that are used in the formation of biodegradable scaffolding (column 7, Line 5, D3). Therefore the subject matter of claims 1-5,7,11,12,23-28 is not novel according to Article 54 EPC.

3.5 Document D6 (cited from the knowledge of the examiner) discloses a prepolymer composition prepared by reacting a 400 molecular weight Polyoxypropyleneglycol (PPG) and castor oil with MDI into a prepolymer A having a viscosity of 4000 cps. Prepolymer B having a viscosity of 400 cps is based on MDI and a 400 PPG (example 1, D6). These prepolymers are reacted with different lactone derived polyester polyols as depicted in table 1, D6. The resulting polymers are used in biomedical devices. Therefore the subject matter of claims 1-4,6,11,12,23,24,26 is not novel according to Article 54 EPC.

#### **4 Claims 8-10,14-22**

4.1 The combination of the features of dependent claims 8 -10 with claims 14-22 is neither known from, nor rendered obvious by, the available prior art. A new independent claim may be drafted to include these features, bearing in mind that the features known in combination should be placed in the preamble of such a claim in accordance with Rule 43 (1) EPC.

#### **5 Article 123 (2)**

5.1 In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123 (2) EPC, the applicant is requested to clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based.

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.



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# SUPPLEMENTARY PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention EP 03 73 9861  
shall be considered, for the purposes of subsequent  
proceedings, as the European search report

Application Number

## DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 5 578 662 A (BENNETT ET AL) 26 November 1996 (1996-11-26)  * column 2, line 25 - column 8, line 46; claims 1,3,9,10; examples 9,14-18 * -----	1-7, 11-13, 23,24,26	C08G18/32 C08G18/80 A61L27/18
X	WO 02/36695 A (BASF DRUCKSYSTEME) 10 May 2002 (2002-05-10) * page 4, line 20 - page 7, line 30 * * page 16, line 4 - page 19, line 38; claims 1-6 * -----	1-5	
X	US 6 376 742 B1 (ZDRAHALA ET AL) 23 April 2002 (2002-04-23) * column 2, line 48 - column 4, line 16 * * column 6, line 64 - column 10, line 2; claims 1-16; examples 3,7 * -----  -/-	1-5,11, 12,23-28	
			TECHNICAL FIELDS SEARCHED (IPC)
			C08G A61L

The supplementary search report has been based on the last set of claims valid and available at the start of the search.

## INCOMPLETE SEARCH

The Search Division considers that the present application, or some or all of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for the following claims:

Claims searched completely :

Claims searched incompletely :

Claims not searched :

Reason for the limitation of the search:

see sheet C

3  
EPO FORM 1502 (04/02) (PAC/20)

Place of search <b>The Hague</b>	Date of completion of the search <b>21 February 2006</b>	Examiner <b>Bourgonje, A</b>
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons</p> <p>* : member of the same patent family, corresponding document</p>		



DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (IPC)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
P,X	ZHANG ET AL: "Synthesis, Biodegradability and Biocompatibility of Lysine Diisocyanate-Glucose Polymers" TISSUE ENGINEERING, vol. 8, no. 5, October 2002 (2002-10), pages 771-785, XP008059981 * page 772, column 1, line 9 - page 774, column 2, line 28 * * page 779, column 2, line 1 - page 780, column 1, line 4; figure 2a * -----	1-5,7,10	
			TECHNICAL FIELDS SEARCHED (IPC)



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INCOMPLETE SEARCH  
SHEET C

Application Number  
EP 03 73 9861

Although claims 27,28 are directed to a method of treatment of the human/animal body (Article 52(4) EPC), the search has been carried out and based on the alleged effects of the compound/composition.

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**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

EP 03 73 9861

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

21-02-2006

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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			EP 0693294 A2	24-01-1996
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